

REMARKS

This Preliminary Amendment, filed in conjunction with a Request for Continued Examination ("RCE"), responds to the Final Office Action mailed 27 March 2008. The filing of this Amendment and RCE is permissible under 37 C.F.R. § 1.114. *See* M.P.E.P. § 706.07(h).

Claims 1, 28, and 45-48 have been amended and claims 29-32 have been canceled. Support for these amendments can be found variously throughout the specification, including, for example, page 4, lines 7-22, and FIGS. 4-6. No new matter has been added. Accordingly, claims 1, 4, 5, 7, 12-16, 20-22, 24, 25, 28, 33-39, and 45-60 are presently pending in the application, each of which Applicants believe is in condition for allowance. Applicants respectfully request reconsideration of the application in light of the above amendments and the following remarks.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 1, 28, 45, 46, 47, and 48) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 103

In the Action, the Examiner rejected claims 1, 13-16, 20-21, 28-30, and 45-60 under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 6,626,918 to Ginn et al. (“Ginn”). The Examiner also rejected claims 48-60 under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 6,179,863 to Kensey et al. (“Kensey”). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the reference (or references when combined) must teach or suggest each and every claim element. *See, e.g., In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *accord.* MPEP 2143.03. Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *See In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added).

Independent claims 1, 28, 45, and 46 of the present application recite, *inter alia*, an insertion sheath, a dilator sized to fit in the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, and a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath. Likewise, independent claim 47 of the present application recites, *inter alia*, an insertion sheath, a dilator sized to fit in the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, and a first inlet port located in the distal end of the dilator such that the first inlet port is positionable distally beyond the distal end of the insertion sheath. Similarly, independent claim 48 of the present application

recites, *inter alia*, a vascular insertion assembly comprising a distal end where a first distal hole and an over insertion hole are located, a proximal end where a first indicator and an over insertion indicator are located, an insertion sheath, a dilator sized to fit inside the insertion sheath, the dilator having a distal end positionable distally beyond a distal end of the insertion sheath, and a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath.

Ginn, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claims 1, 28, 45, 46, 47, and 48. For example, at the very least, Ginn fails to disclose, teach, or suggest a “dilator” having a “first distal hole” or a “first inlet port” that is “located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath.” Instead, Ginn merely discloses an obturator having a hole that is only positionable proximally relative to the distal end of the sheath.

For example, Ginn clearly states that “sheath 12 may be advanced over a guidewire or other rail (not shown) previously positioned through the incision 92 into the blood vessel 90.” Col. 6, lines 40-44. As made clear in Ginn, sheath 12 is not inserted into a blood vessel using a dilator, but rather, sheath 12 is positioned in a blood vessel using a guidewire or rail that is already located in the blood vessel prior to introducing the sheath. Additionally, as clearly shown in FIG. 3, sheath 12 is positioned in blood vessel 90 without a dilator or even an obturator. *See also* col. 6, lines 36-41 (“As best seen in FIG. 3, the sheath 12 may be inserted or otherwise positioned within a blood vessel 90, *i.e.*, through an incision, puncture, or other opening 92 that extends from a patient’s skin 94”).

Ginn additionally discloses that an obturator is placed within the sheath only after the sheath has already been inserted into a blood vessel. For example, Ginn clearly describes that “[a]fter the procedure is complete, the device(s) may be removed from the sheath 12, and the obturator 14 inserted through the hemostatic valve (not shown) into the lumen 16”). This passage in Ginn makes it clear that obturator 14 is not a dilator. The passages in Ginn cited by the Examiner in the Office Action likewise confirm that obturator 214 in Ginn is not a dilator. *See, e.g.*, col. 8, lines 52-58 (“As best seen in FIGS. 12 and 13, during use of the apparatus 210, the sheath 212 may be disposed within a blood vessel 90 through an incision 92. After a procedure is completed using instruments introduced through the sheath 212, the obturator 214 may be inserted into the lumen 216”).

Further, the obturator disclosed in Ginn clearly does not have a “distal hole [that] is positionable distally beyond the distal end of the insertion sheath.” Rather, as disclosed in Ginn, any holes located in the obturator are only positionable underneath the sheath positioned proximally from the distal end of the sheath, as clearly shown, for example, in FIGS. 7-9 and 11-17B. *See also* col. 8, lines 15-48 (“The sheath 212 includes first and second sets of side ports 242, 250, each set preferably including a plurality of side ports that communicate with the lumen 216. ... Preferably, when the obturator 214 is fully received in the sheath 212 ... the first and second sets of distal openings 249, 253 are axially aligned with the first and second sets of side ports 242, 250, respectively.”).

Accordingly, because Ginn fails to disclose, teach or suggest each and every limitation of independent claims 1, 28, 45, 46, 47, and 48, a *prima facie* anticipation rejection has not been established. *See, e.g., Verdegaaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2

USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1566 (Fed. Cir. 1989) (“The identical invention must be shown in as complete detail as is contained in the . . . claim.”).

Kensey also clearly fails to disclose, teach, or suggest each and every element recited in independent claim 48. For example, at the very least, Kensey fails to disclose, teach, or suggest a “vascular insertion assembly comprising . . . a proximal end where a first indicator **and** an over insertion indicator are located.” Instead, Kensey merely discloses a single proximal port.

For example, Kensey explains that inlet port 304 in insertion sheath 28 (*see, e.g.*, FIG. 27) and inlet port 404 in dilator 400 (*see, e.g.*, FIG. 28) are each in fluid communication with a single “sideport 28D.” Therefore, since Kensey merely discloses a single outlet (*i.e.*, sideport 28D), Kensey clearly fails to disclose, teach, or even suggest both a first indicator and an over insertion indicator located at a proximal end of the vascular insertion assembly.

Accordingly, because Kensey fails to disclose, teach or suggest each and every limitation of independent claim 48, a *prima facie* case of obviousness has not been established. *See, e.g., In re Royka*, 490 F.2d 981, 985 (CCPA 1974) (holding that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art); *accord.* MPEP § 2143.03 (“To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations.”) (emphasis added). Applicants therefore respectfully request withdrawal of this rejection.

Moreover, aside from the novel limitations recited therein, each of claims 4, 5, 7, 12-16, 20-22, 24, 25, 33-39, and 49-60 are also allowable at least by virtue of their dependency upon allowable base claims 1, 28, 45, 46, 47, and 48. Applicants respectfully request, therefore, that the rejection of claims 4, 5, 7, 12-16, 20-22, 24, 25, 33-39, and 49-60 under 35 U.S.C. § 103 be withdrawn, and these claims be allowed.


Conclusion

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Respectfully submitted,

Dated: _____

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